APPLICANT'S REMARKS

1. <u>Status of the Claims</u>

Claims 1 to 8 and 11 to 16 are pending. Claims 1, 3, and 4 are currently amended. Claims 2, 9, and 10 are withdrawn. Claim 5 is original. Claim 6 is canceled. Claims 7, 8, and 11–16 are as previously presented.

The Applicant respectfully submits that claim 2 is directed to presently non-elected species of the invention of Group I and should be withdrawn from current prosecution, but considered for rejoinder when appropriate. The Applicant requests clarification of this issue on the record.

2. <u>Claims 1–4 Rejected under 35 U.S.C. 102(e) based on LANDFIELD</u>

Claims 1–4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2005/071088 (LANDFIELD).

To anticipate a claimed method, a reference must (1) disclose each and every element of the claimed method, and (2) enable one of ordinary skill in the art to use the claimed method without undue experimentation. (*In re* Gleave, 560 F.3d 1331, 1334–5 (Fed. Cir. 2009)). "The disclosure [in a reference] need not be express, but may anticipate by inherency." (Continental Can v. Monsanto, 948 F.2d 1264, 1268 (Fed. Cir. 1991))

Nonetheless, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic <u>necessarily</u> flows from the teachings of the applied prior art." (*Ex parte* Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original))

The Examiner asserts that LANDFIELD discloses a method of assessing a state of Alzheimer's disease comprising detecting neurosecretory protein VGF. The Examiner acknowledges that LANDFIELD does not explicitly disclose VGF having the molecular mass recited in claim 1 or the sequence as recited in claim 3. However, the Examiner argues that "it is inherent that the neurosecretory protein VGF as disclosed in LANDFIELD has a molecular mass [as recited in claim 1] and an identical sequence [as recited in claim 3]."

The Applicant respectfully disagrees with the Examiner and submits that claims 1–4 are not explicitly or inherently anticipated by LANDFIELD. Specifically, the presently claimed use of a specific polypeptide (*i.e.*, a polypeptide of a particular weight and sequence) to assess Alzheimer's disease does not necessarily flow from the disclosure of LANDFIELD.

LANDFIELD discloses the *Vgf* gene shows a highly significant, age-dependent decrease in expression. LANDFIELD also discloses that the expression level of *Vgf* gene is significantly correlated with memory performance. Therefore, LANDFIELD concludes that *Vgf* gene could serve as a biomarker for age-related neurodegenerative diseases. Finally, LANDFIELD claims to provide for both the polynucleotides (*i.e.*, genes) and polypeptides

encoded by the genes. Thus, LANDFIELD arguably claims that the protein encoded by *Vfg*

gene, which is full-length, precursor Vgf protein, can also likewise serve as a biomarker.

The Applicant notes that human, full-length, precursor VGF protein has a predicted

molecular weight of 6727 Da and is 615 a.a. long.

In contrast to LANDFIELD, the present application claims a method of assessing the state

of Alzheimer's disease in a subject comprising detecting: a polypeptide having an observed

molecular mass of 4824 ± 20 Da (claim 1); a polypeptide of SEQ. ID. NO:17 (claim 3);

and/or at least contiguous 5 amino acids of a polypeptide of SEQ. ID. NO:17 (claim 4).

The Applicant respectfully submits that the Examiner has not explained how LANDFIELD's

disclosed use of the protein encoded by *Vgf* gene as a general biomarker for age-related

neurodegenerative diseases necessarily or inevitably provides the presently claimed use of

a lighter and shorter polypeptide in particular as a specific biomarker for Alzheimer's

disease.

Therefore, the Applicant respectfully requests that the §102(e) rejection of claims 1–4 be

reconsidered and withdrawn.

3.   Rejection of Claims 1–8 and 11–16 under 35 U.S.C. 103(a) based on

       DELACOURTE in view of LANDFIELD

Claims 1–8 and 11–16 are rejected under 35 U.S.C. 103(a) based on U.S. Patent

Application No. 2005/0175626 (DELACOURTE) in view of LANDFIELD.

For determining obviousness, all words in a claim must be considered in judging the

patentability of that claim against the prior art (*In re* Wilson, 424 F.2d 1382, 1385, 165

USPQ 494, 496 (CCPA 1970)).

The Examiner asserts that DELACOURTE discloses a method of assessing a state of

Alzheimer's disease comprising separating polypeptides from CSF and detecting said

polypeptides via SELDI-TOF MS. The Examiner acknowledges that DELACOURTE fails to

disclose a method wherein the polypeptide being tested is neurosecretory protein VGF.

The Examiner relies of LANDFIELD to supply a method comprising detecting

neurosecretory protein VGF.

For the reasons stated above, the Applicant respectfully submits that LANDFIELD does not

disclose or even suggest detecting the specific polypeptide of the present claims.

Combining of LANDFIELD with DELACOURTE does not cure this deficiency because

DELACOURTE is only concerned with Aβ polypeptides. DELACOURTE is silent regarding

the polypeptide of the presently claimed methods.

Therefore, the Applicant respectfully submits that, even assuming *arguendo* that the references may be properly combined, the combination of LANDFIELD and DELACOURTE does not disclose or even suggest all the features recited in the present claims.

In light of the foregoing, the Applicants respectfully request that the §103(a) rejection of claims 1–8 and 11–16 be reconsidered and withdrawn.

Respectfully submitted,

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